

## REMARKS

Claims 1 to 31 are currently pending in the application. Claims 1 to 31 have been rejected. By this amendment, Applicants have amended claims 1, 11, 14 and 26, canceled claims 12, 13 and 23 without prejudice and added new claim 32. No new matter has been added by the amendments, all of the amendments having full support in the specification and drawings as filed. In view of the above amendments and the following remarks, Applicants respectfully submit that this application is in condition for allowance. Accordingly, reconsideration and a timely notice of allowance are respectfully requested.

### Claim Amendments

Claim 1 has been amended to recite, “wherein said female component comprises a face having castellations; and wherein leak paths are provided between said castellations in the event that a standard male connector is butted against said face.” Claim 11 has been amended to recite “wherein said different female connector comprises a face having castellations, whereby leak paths are provided between said castellations in the event that a standard male connector is butted against said face.” Full support for these amendments is found in the specification and drawings as filed, including for example, on pg. 20, lines 17 to 34 and in figs. 3b, 6a and 7a and in claim 23.

Claim 11 has also been amended to recite the limitations of claims 12 and 13. Claim 14 has been amended to depend from claim 11. Claim 26 has been amended to correct a typographical error.

No new matter has been added by the amendments. Entry of the amendments to the claims is respectfully requested.

### Rejections Under 35 U.S.C. §102

Claims 1 to 16, 18 to 27, 29 and 31 are rejected under 35 U.S.C. §102(b) as being anticipated by Segal et al. (U.S. Patent No. 6,402,207). Claims 12, 13 and 23 have been canceled without prejudice, but Applicants address this rejection as to the remaining claims. In view of the

amendments to claims 1 and 11, Applicants respectfully traverse this rejection.

Claim 1 as amended recites, “wherein said female component comprises a face having castellations; and wherein leak paths are provided between said castellations in the event that a standard male connector is butted against said face.” Claim 11 as amended recites “wherein said different female connector comprises a face having castellations, whereby leak paths are provided between said castellations in the event that a standard male connector is butted against said face.” Applicants respectfully submit that Segal et al. fail to teach or suggest these limitations.

The present invention is directed to a system for preventing misconnections between different applications of medical tubing. Typically, medical tubing of all applications is connected using male and female luer fittings. The present invention has a connector system with male and female connectors that may utilize luer similar cones and sockets. The male and female connectors form a key that prevents interchangeability between different applications. Castellations on the female component and leak paths between the castellations prevent anyone from inserting a standard male luer fitting into the female component. As explained in the specification, on pg. 20, lines 17 to 34, the castellations are an obstacle to inadvertent and even malicious misconnection between tubing of different applications.

While Segal et al. state generally that misconnections will cause leakage, there is no teaching or suggestion of specific structure to prevent a male luer fitting from being used in connection with the fittings taught by Segal et al. See Segal, col. 6, line 65 to col. 7, line 10. Accordingly, Applicants submit that claims 1 and 11 are patentable over Segal et al. on this basis.

Additionally, claim 1 recites that “said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues.” Applicants continue to respectfully submit that Segal et al. fail to teach or suggest this limitation. Applicants hereby incorporate by reference the remarks previously submitted in the Amendment and Response to Office action filed on September 6, 2007.

Additionally, claim 11, as amended, recites standard male and female connectors each having standard connectors and different connectors. The “standard connectors are 6% luer

connectors” and the “different connectors are reduced diameter 6% conical connectors”. Conical connectors, which are familiar to the medical industry, are easy and convenient to use and are well-tried and tested.

Segal et al. teach a variety of complementary shapes and sizes, such as those illustrated in Fig. 5, Segal et al. do not teach the use of conical connectors. Moreover, Applicants respectfully submit that one skilled in the art would have no motivation to modify Segal et al. to use conical connectors as claimed.

Claims 2 to 10, 14 to 16, 18 to 27, 29 and 31 depend from claims 1 and 11 and by definition contain all of the limitations of claims 1 and 11 respectively. Accordingly, Applicant respectfully submits that claims 2 to 10, 14 to 16, 18 to 27, 29 and 31 are patentable over Segal et al. for the reasons given above for claims 1 and 11 as well as because of the additional limitations contained therein.

For example, claim 2 further recites “wherein said application affordance comprises a shape of the grip that is suggestive of a part of a human body for which the application is intended.” The Examiner states that Segal et al. teach this limitation in col. 8, lines 33 to 49 and col. 2, lines 12 to 19 and col. 5, lines 31 to 46 and Figs. 5 and 7. The portions cited by the Examiner are reproduced below for convenience:

Col. 8, lines 33 to 49:

The foregoing safety medical connectors are designed to be interposed between existing devices for medical infusions, injections, or aspirations. An additional feature of the present invention is the fusion of a half connector as illustrated in FIG. 1 into a standard medical connector or device. FIGS. 7A through 7D illustrate the incorporation of a safety connector half into an epidural catheter connector 500, which in turn is connected to an epidural catheter 505. Any of the mating and locking configurations of the present invention, for example the rectangular surface feature 510, can be incorporated into the end of the epidural catheter connector. The epidural catheter connector in turn mates with a complementary safety connector half 520. This connector half includes a complementary shaped surface feature that ensures that only medications intended for epidural delivery are injected through the epidural catheter, since only a specific surface feature 510 can mate with the connector half 520.

Col. 2, lines 12-19:

The present invention addresses this problem by replacing the universal connector with unique specially configured male/female connector pairs, each coded for use with only one type of medical catheter or device (e.g., peripheral intravenous catheter, central venous catheter, arterial catheter, epidural catheter, dialysis catheter).

Col. 5, lines 31 to 46:

The illustrated medical connector portions 1, 3 of the invention are designed to be application or path-specific. The male or first connector portion 1 of the medical connector 40 is configured to mate with only one type of mating surface, although selected others are also contemplated, and will not mate with other female type connectors. Thus a connector designated, for example, for epidural catheter injections is generally incapable of connection to a syringe intended for intravenous injection absent the specially configured surface feature. The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from distinctive markings on the outer surfaces of the half connectors. These markings can include textured features, color coding and/or text labels, such as labels 70.

Applicants respectfully submit that none of the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest “a shape of the grip that is suggestive of a part of a human body for which the application is intended” as claimed. Applicants respectfully submit that Segal et al. simply do not anticipate this limitation nor would one skilled in the art be motivated to modify the teachings of Segal et al. to reach “a shape of the grip that is suggestive of a part of a human body for which the application is intended.”

Claim 3 further recites “wherein a first application is neuraxial, and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs.” One embodiment of such a grip shape is shown in Fig. 5a. The Examiner cites to the portions reproduced above, col. 8, lines 33 to 49, col. 2, lines 12 to 19, col. 5, lines 31 to 46 and to Figs 5, 7 and 7A for teaching this limitation. Applicants respectfully submit that neither the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitation. A review of Fig. 5 reveals a plurality of different cross sectional shapes of the mating ends and Fig. 7A reveals a cylindrical grip having an indented portion. Applicants respectfully submit that the grip shown in Fig. 7A is not suggestive of a human spine and ribs as

claimed and that the portions cited by the Examiner do not anticipate the grip shape that “is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs.”

Claim 4 further recites, “wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows.”

Claim 5 further recites “wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon.” In rejecting both claims 4 and 5, the Examiner cites to Figures 5 and 7, col. 6, lines 37 to 64, and to the portions reproduced above, col. 8, lines 33 to 49, col. 2, lines 12 to 19, and col. 5, lines 31 to 46. Col. 6, lines 37 to 64 is reproduced below for convenience:

FIGS. 5A through 5D illustrate still other embodiments of the surface features which can be formed on the mating ends of the medical connectors in accordance with the present invention. In each case, a complementary pair of protuberances and recesses are incorporated into the medical connectors. In FIG. 5A, the protuberances can have a variety of geometric shapes, which are arranged coaxially around the lumen 10. The shapes of the surface features can further include a triangle 100, square 105, pentagon 110, hexagon 115, or other regular polygon or quadrilateral shape. As is readily apparent to those of ordinary skill, each illustrated surface feature can replace the cylindrical protuberance 15 of FIG. 1. The raised surface features fit into a complementary shaped and sized cavity formed in the other medical connector half.

FIGS. 5B and 5C illustrate employing raised surface features that have varying sizes. In these instances, the lumen 10 is surrounded by a cylindrical protuberance of small 130, intermediate 135, or larger 140 diameter, or alternatively a regular polygon of small 145, intermediate 150, or larger 155 size. FIG. 5D illustrates employing radial projections in an outer surface of the connector half, to effectuate radial pin indexing. In this configuration, radially spaced pins 160 are arranged circumferentially about the protuberance 15. These pins uniquely mate with complementary slots 165 arranged radially within the walls of the cavity 25 formed in the other connector half.

Applicants respectfully submit that neither the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitations of claims 4 and 5. Segal et al. do not anticipate a grip shaped as “generally cylindrical having alternating frusto-conical sections

suggestive of a bellows” or a grip shaped as “generally cylindrical with bulges down its length suggestive of the human colon.”

Claim 8 further recites, “wherein said method of interconnection comprises a twisting step; and wherein said mechanism affordance comprises a wing of said grip.” Claim 9 further recites, “wherein said method of interconnection comprises a pushing step; and wherein said mechanism affordance comprises a waist of said grip.” Claim 10 further recites, “wherein said method of interconnection comprises a locking step; and wherein said mechanism affordance comprises a button of said grip.” The Examiner cites the same elements of Segal et al., namely Figure 2, elements 29 and 35 as teaching all of the limitations of claims 8, 9, and 10. Applicants respectfully submit that elements 29 and 35 are not wings, a waist or a button, and therefore fail to teach or suggest the above limitations of claims 8 to 10. Moreover, Applicants submit that the rejection is improper as citing the same elements for teaching three different structures.

Accordingly, Applicants respectfully request that the rejection of claims 1 to 16, 18 to 27, 29 and 31 under 35 U.S.C. §102(b) be withdrawn.

### **Rejections Under 35 U.S.C. §103(a)**

The Examiner rejected claims 17 and 28 to 30 under 35 U.S.C. §103(a) as being unpatentable over Segal et al. (U.S. Patent No. 6,402,207 in view of Moberg et al. (U.S. Patent No. 6,659,980). Applicants respectfully traverse this rejection.

Claims 17 and 28 to 30 depend from claim 11, and by definition contain all of the limitations of claim 11. As explained above with regard to claim 11, Applicants respectfully submit that Segal et al. fail to teach or suggest “wherein said different female connector comprises a face having castellations, whereby leak paths are provided between said castellations in the event that a standard male connector is butted against said face.” Applicants respectfully submit that Moberg et al. fail to remedy the defects of Segal et al.

Moberg is directed to improvements in infusion pumps. The Examiner cites to Moberg et al. for teaching ultrasonic welding and adhesion. However, Applicants respectfully submit that Moberg et al. fail to teach or suggest wherein “wherein said different female connector comprises

a face having castellations, whereby leak paths are provided between said castellations in the event that a standard male connector is butted against said face.”

Accordingly, Applicants respectfully submit that claim 11 is patentable over Segal et al. and Moberg et al., both alone and in combination. Applicants further submit that claims 17 and 28 to 30 are patentable over Segal et al. and Moberg et al. for the reasons given above for claim 11 as well as because of the additional limitations contained therein.

Accordingly, Applicants respectfully request that the rejection of claims 17 and 28 to 30 under 35 U.S.C. §103(a) be withdrawn.

### **New Claim 32**

Applicants have added new claim 32 which recites “wherein the grip is defined on a threaded collar on the male component, the female component having a flange forming thread elements engageable with the collar to lock the collar; and wherein the collar is axially slidable between limits on said male component and is rotatably free thereon.” Full support from new claim 32 is found in the specification and drawings as filed, for example, on page 9, line 34 to page 10, line 7. No new matter has been added and entry of new claim 32 is respectfully requested.

Claim 32 depends from claim 1 and by definition contains all of the limitations of claim 1. As explained above with regard to claims 1 and 11, Applicants respectfully submit that Segal et al. and Moberg et al., considered alone and in combination, fail to teach or suggest “wherein said female component comprises a face having castellations; and wherein leak paths are provided between said castellations in the event that a standard male connector is butted against said face” as recited in claim 1. Therefore, Applicants respectfully submit that claim 32 is patentable over Segal et al. and Moberg et al. for the reasons given above for claim 1 as well as because of the additional limitations contained therein.

### **CONCLUSION**

In view of the above amendments and remarks, Applicants believe that all pending claims

are in condition for allowance and such action is earnestly requested. If the present remarks do not place the application in condition for allowance, then the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants' representative.

Fees of \$930 (\$525 for a three month extension of time, and \$405 for a Request for Continued Examination) are believed due with this communication. The Commissioner is hereby authorized to charge payment of this fee and any other fees due with this communication to Deposit Account No. 19-2090.

Respectfully Submitted,  
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